

CLEAN SUBSTITUTE SPECIFICATION

Device For Dosing A Product That Is Intended To Be Applied To The Skin

The present invention concerns the metering of a product for topical application such as a medication. The invention is intended to provide a new device for metering products intended to be applied to the skin, in particular pharmaceutical or cosmetic products. The invention relates more particularly to a device taking the form of an applicator stick, the graduations of which allow users to determine the precise quantity of medication to be applied to the skin as a function of the surface area to be treated.

With regard to medication intended to be applied to the skin, it is known that the efficacy of topical medication depends *inter alia* on their dosage. Whether formulated as a cream, ointment, foam, liquid, or as adhesives such as patches, the medication intended for topical application is not packed in a device allowing optimum metering. Thus when the medication intended for topical application is packed in the form of a tube or simple bottle, the precise dose to be applied of said drug cannot be calibrated by the user.

There are however numerous metering distributors. Some have a siphon-like device which require pumping-like manipulation by the user; they often comprise a high number of parts which makes production difficult. Other metering distributors are fitted with a piston-type device but as the quantity of product supplied is a function of the pressure exerted by the user, these are not reliable.

Furthermore these metering distributors are fitted with a system allowing issue of only a single dose of the product.

To remedy the above drawbacks, the applicant has now developed an optimum device for metering a medication intended to be applied to the skin, where the quantity of medication applied is precise and can be modulated as a function of the surface of the skin to be treated; this allows better efficacy of the treatment.

This aim is achieved thanks to a device for metering a product intended to be applied to the skin, in particular a pharmaceutical or cosmetic composition, comprising an applicator stick with a longitudinal groove along which is defined a series of compartments, said groove being able to hold a quantity of medication corresponding to a defined surface area of the skin to be treated, the quantity being defined by one or more compartments.

Advantageously the applicator is fitted with graduations which, from one end of the groove corresponding to the start of the first compartment and for the following compartments, define the quantity of medication in the compartments of the groove.

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Following a particular method of implementation, the device of the present invention comprises at least two, preferably at least three and most preferably four compartments.

Said compartments may have the same or different dimension and in the latter case 10 compartments of increasing dimension are preferred. The term dimension here preferably means the length of the compartment but a variant of the invention consists of varying the depth or width of the groove continuously or from one compartment to the other.

15 Preferably the graduation of the applicator stick is selected from a graduated scale, protuberances, notches, a set of colours or a combination thereof. The graduation of the applicator stick may be arranged inside and/or outside the groove.

According to a particular method of implementation, the device preferably comprises at 20 least at one end of the applicator stick, a surface designed for manipulation. This may for example be a flared portion at one end of the applicator stick.

According to preferred embodiments of the invention:

- the first compartment is able to contain a quantity of medication corresponding 25 approximately to an area of 0.8 to 1.2% of the total surface of the body, preferably around 1% of the total surface of the body;
- the first and second compartments are able to contain a quantity of medication corresponding approximately to an area of 2.4 to 3.6% of the total surface of the body, preferably around 3% of the total surface of the body;
- the first, second and third compartments are able to contain a quantity of medication corresponding approximately to an area of 4.8 to 7.1% of the total surface of the body, preferably around 6% of the total surface of the body;
- the first, second, third and fourth compartments are able to contain a quantity of 30 medication corresponding approximately to an area of 7.2 to 10.8% of the total surface of the body, preferably 9% of the total surface of the body.

The device according to the invention is remarkable in that it can be reused by the patient, it is adapted to any form of presentation of the drugs for topical application, for example liquid, semi-liquid, gel, ointment, cream or powder.

5 The device according to the invention can be made of any impermeable material meeting hygiene requirements, such as glass, metal, flexible or rigid plastics.

A specific application of the device according to the invention relates to metering of a drug intended to treat psoriasis, said drug preferably being Silkis (calcitriol ointment).

10 For this application:

- the first compartment is able to contain a quantity of Silkis (calcitriol ointment) of around 0.35 to 0.54 grams (g), preferably 0.45 grams;

- the first and second compartments are able to contain a quantity of Silkis (calcitriol ointment) of around 1.08 to 1.62 grams, preferably 1.30 grams;

15 - the first, second and third compartments are able to contain a quantity of Silkis (calcitriol ointment) of around 2.16 to 3.20 grams, preferably 2.60 grams;

- the first, second, third and fourth compartments are able to contain a quantity of Silkis (calcitriol ointment) of around 3.24 to 4.86 grams, preferably 3.90 grams;

20 Other advantages and features of the invention will appear from the example below concerning a device for metering Silkis (calcitriol ointment) for the treatment of psoriasis, given as an illustrative example and not to be interpreted as limiting the scope of the invention, and in which reference will be made to the attached drawings in which:

25 - Figure 1 shows an oblique top view of the metering device.

- Figure 2 shows a top view of the metering device.

- Figure 3 shows a profile view of the metering device.

- Figure 4 shows a vertical section through the metering device.

30 Figures 1, 2 and 3 represent a metering device according to the invention comprising an applicator stick (1) of oblong shape provided with graduations formed by protuberances (4). The applicator stick comprises a longitudinal groove (2) fitted with a series of compartments (3) and having at one end a flared circular part (5), which facilitates handling of said applicator stick.

In the present example the applicator stick (1) is of oblong shape measuring 158mm long, 32mm wide at the level of the end with the circular portion (5) and 17mm wide at the other end. The groove (2), of width 7mm and depth 2mm, extends along a longitudinal axis over 126mm. This groove is divided into four compartments (3a, 3b, 5 3c and 3d) by protuberances (4). The first compartment (3a) defines a volume of 7mm width, 2mm depth and 14mm length. The second compartment (3b) defines a volume of 7mm width, 2mm depth and 28mm length. The third (3c) and fourth (3d) compartment each define a volume of 7mm width, 2mm depth and 42mm length.
Figures 3 and 4 show a metering device according to the invention with a longitudinal
10 bulge (6) on the lower face of the applicator stick (1), which constitutes the base of the groove (2) or a means allowing inclination of the device when flat.

Example 1

15 1) Definition of body surfaces to be treated

To define the body surfaces to be treated in the treatment of psoriasis, the applicant uses a proposition derived from Wallace's 9% rule. The applicant has thus determined the following body surface area percentages (expressed in relation to the total surface area of the body):

20 - inguinal fold: between abdomen and thigh = 1%
- gluteal fold = 1% (3% of back)
- lumbar region = 3%
- face = 9%: 1% per ear, 1% per eyebrow, 1% chin, 1% per nasal fold, 2% forehead

25 2) Determination of Silkis (calcitriol ointment) dose

Given that the maximum dose of Silkis (calcitriol ointment) that can be used per day is 30 grams in two applications and the maximum treatable surface area of the body is 35% of the total body surface, the applicant has established the optimum dose of Silkis (calcitriol ointment) as $30/2/35\%$ or 0.43 grams per percentage body surface to be
30 treated per application.

Table 1 shows the correlation between the percentage of body surface to be treated and the Silkis (calcitriol ointment) dose.

% body surface	1%	3%	6%	9%
Silkis (calcitriol ointment) dose	1	3	6	9
Quantity of Silkis (calcitriol ointment) to be applied (in g)	0.45	1.30	2.60	3.90